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selected from the group consisting of gluconic acid and salts thereof.

## REMARKS

### **I. Introduction**

In response to the pending Office Action, Applicants have amended claim 1 so as to address the rejection of claim 1 under 35 U.S.C. § 112, second paragraph. The amendment to claim 1 is intended to clarify the subject matter of claim 1, and in no way intended to further limit the scope of the claim.

Applicants acknowledge with appreciation the indication of allowable subject matter being recited by claims 2, 3 and 6-11.

Finally, Applicants respectfully request reconsideration of the rejected claims for the reasons set forth below.

### **II. The Rejection Of The Claims Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-12 were rejected under 35 U.S.C. § 112, second paragraph, for being indefinite due to the recitation of the term "one kind of". The term objected to by the Examiner has been eliminated from the claim. Accordingly, it is respectfully submitted that the claims are in full compliance with the requirements of 35 U.S.C. § 112, second paragraph.

### **III. The Rejection Of Claims 1, 4 And 5 Under 35 U.S.C. § 102**

Claims 1, 4 and 5 were rejected under 35 U.S.C. § 102(a) as being anticipated by JP 10227755 to Toshihiko. Applicants respectfully traverse this rejection for the

following reasons.

As recited by pending claim 1, the present invention relates to a glucose sensor having a reaction layer containing pyrrolo-quinoline quinone dependent glucose dehydrogenase (PQQ-GDH) and at least one **additive** selected from the group consisting of gluconic acid and salts thereof. As set forth in the specification, the storage stability of a sensor having a reaction layer containing PQQ-GDH is significantly improved by adding gluconic acid and/or a salt thereof. The gluconic acid and/or salt thereof protects the PQQ-GDH from changes in the environment, for example, changes in temperature and humidity, thereby improving storage capabilities. For further details, see page 7 of the specification.

Turning to the cited prior art, ***Toshihiko does not disclose a reactive layer having an additive consisting of gluconic acid*** or a salt thereof. As noted by the Examiner, Toshihiko discloses that the reactive layer contains dehydrogenase. However, while the Examiner's assertion that gluconic acid is a product of the activity of glucose dehydrogenase and glucose, in the device of Toshihiko, gluconic acid is not produced unless a sample containing glucose, for example blood, is supplied to the sensor. In other words, the sensor of Toshihiko has to be utilized to produce the gluconic acid. It is a product of the reaction, not an additive.

In contrast, in the present invention as recited by claim 1, the gluconic acid or salt thereof is an ***additive***, which is added to the reaction layer during formation of the sensor so as to improve the storage capabilities of the sensor. Clearly, Toshihiko does not disclose adding a gluconic acid as an additive to the reaction layer. As stated, any gluconic acid present in the device of Toshihiko is a result of the reaction process

occurring when utilizing the sensor.

Accordingly, as anticipation under 35 U.S.C. § 102 requires that each element of the claim in issue be found, either expressly described or under principles of inherency, in a single prior art reference, ***Kalman v. Kimberly-Clark Corp.***, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983), and Toshihiko does not disclose a sensor having a reaction layer containing PQQ-GDH and an additive containing gluconic acid and/or a salt thereof, it is clear that Toshihiko does not anticipate claim 1, or any claim dependent thereon.

**IV. All Dependent Claims Are Allowable Because The Independent Claim From Which They Depend Is Allowable**

Under Federal Circuit guidelines, a dependent claim is nonobvious if the independent claim upon which it depends is allowable because all the limitations of the independent claim are contained in the dependent claims, ***Hartness International Inc. v. Simplimatic Engineering Co.***, 819 F.2d at 1100, 1108 (Fed. Cir. 1987).

Accordingly, as claim 1 is patentable for the reasons set forth above, it is respectfully submitted that all pending dependent claims are also in condition for allowance.

**V. Request For Notice Of Allowance**


Having fully responded to all matters raised in the Office Action, Applicants submit that all claims are in condition for allowance, an indication for which is respectfully solicited.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicants' attorney at the telephone number shown below.

Respectfully submitted,

MCDERMOTT, WILL & EMERY

Date: 4/17/02

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claim 1 has been amended as follows:

1. (Amended) A glucose sensor comprising: an electrically insulating base plate; an electrode system including at least a working electrode and a counter electrode formed on said base plate; and a reaction layer containing at least pyrrolo-quinoline quinone dependent glucose dehydrogenase, formed in contact with or in the vicinity of said electrode system, wherein said reaction layer contains at least one [kind of] additive selected from the group consisting of gluconic acid and salts thereof.